

REMARKS

Claims 1-13, 16-22, 29-34, 43, 45 and 81-83 are pending in the present application. Claims 1-3, 6, 8-13 and 17 are rejected under 35 USC § 102(e). Claims 4, 5, 7, 9-13, 14-22, 29-34, 43 and 81-82 are rejected under 35 USC § 103(a). Applicants respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks below.

The Amendments to the Specification

Applicants have amended the title so that it more accurately reflects the subject matter of the claims currently pending in the application.

The Amendments to the Claims

Without prejudice to Applicants' rights to present claims of equal scope in a timely filed continuing application, to expedite prosecution and issuance of the application, Applicants have amended Claims 1, 4-8, 10, 13, 19, 29-34, 43 and 45 and cancelled Claims 2, 3, 9, 11, 12, 16-18, 20-22 and 81-83. Applicants have also presented new Claim 84. The amended claims and the new claims are supported by the specification.

Claim 1 has been amended to recite "depositing a physiologically active compound onto a substrate having first and second ends," which is supported, e.g., at page 25, line 28 to page 26, line 4; page 37, lines 6-8; page 40, line 25 to page 41, line 5; FIG. 7. Claim 1 has also been amended to recite "generating a moving heating zone that traverses from the first end to the second end of the substrate, thereby sequentially heating compound exposed to the heating zone to produce a vapor," which is supported, e.g., at page 18, lines 24-27; page 39, line 22 to page 40, line 28.

Claim 19 has been amended to recite "depositing a physiologically active compound onto a substrate," which is supported, e.g., at page 25, line 28 to page 26, line 4; page 37, lines 6-8; FIG. 7. Claim 19 has also been amended to recite "moving a heating zone with respect to the compound deposition area to progressively vaporize compound exposed to the heating zone" which is supported at page 40, lines 1-2 and 10-11; page 18, lines 24-27; page 39, line 22 to page 40, line 28.

New Claim 84 is directed to a method for delivering a physiologically active compound to a patient and recites “depositing a physiologically active compound onto a substrate,” which is supported, e.g., at page 25, line 28 to page 26, line 4; page 37, lines 6-8; FIG. 7. Claim 84 also recites “moving a heating zone with respect to the substrate to progressively vaporize compound exposed to the heating zone,” which is supported, e.g., at page 40, lines 1-2 and 10-11; page 18, lines 24-27; page 39, line 22 to page 40, line 28. Claim 84 also recites “allowing the vapor to condense to form an aerosol,” which is supported, e.g., at page 4, lines 13-15; page 7, lines 24-27. Claim 84 also recites “administering the resulting aerosol to a patient,” which is supported, e.g., at page 7, line 27; page 10, lines 8-9.

The amendments to the claims do not introduce new matter. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter the amendments to the claims and allow all amended claims.

The Rejection under 35 U.S.C. 102

Claims 1-3, 6, 8-13 and 17 are rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,783,753 to Rabinowitz et al. (“Rabinowitz et al.”). Office Action at 2-3.

Applicants respectfully disagree in view of the amended claims. As set forth above, Claim 1 is amended to recite a method for delivering a physiologically active compound to a patient comprising “depositing a physiologically active compound onto a substrate having first and second ends; generating a moving heat zone that traverses from the first end to the second end of the substrate, thereby progressively heating compound exposed to the heating zone to produce a vapor; allowing the cooled vapor to condense to form an aerosol; and administering the resulting aerosol to a patient” (emphasis added). Applicants submit that Rabinowitz et al. does not disclose generating a moving heating zone.

Anticipation requires that “a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.” *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1642 (Fed. Cir. 1996), *see also* MPEP §2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051 (Fed. Cir. 1987). As Rabinowitz et al. fails to disclose generating a moving heating zone, the reference can not be said to anticipate the method of Claim 1. Likewise Claims 4-8 and 13, which depend from Claim 1, are not anticipated for at least the same reasons. Accordingly,

Applicants respectfully request that the Examiner reconsider and withdraw the rejection of these claims under 35 U.S.C § 102(e).

The Rejection under 35 U.S.C. §103(a)

Claims 4, 5, 16 and 18 are rejected under 35 U.S.C. §103(a) as obvious over Rabinowitz et al. Office Action at 3-5.

Applicants respectfully disagree in view of the amended claims. As noted above, Claim 1 is amended to recite a method comprising “generating a moving heat zone that traverses from the first end to the second end of the substrate, thereby progressively heating compound exposed to the heating zone to produce a vapor.” Applicants submit that Rabinowitz et al. does not disclose or suggest generating a moving heating zone.

The present invention is directed to a method for generating and delivering an aerosol formed through vaporization of a compound without significant degradation, and control of the resulting vapors to form aerosols with particles sizes useful for the administration of the compound to a patient. Specification at page 7, lines 24-27. According to the method of the present invention, compounds can be vaporized without significant degradation by limiting the time during which the compound is exposed to an elevated temperature. *Id.* at page 7, line 28 to page 8, line 2; page 9, lines 7-10. In a preferred embodiment, this may be accomplished through the use of a moving heating zone which progressively vaporizes the compound. *Id.* at page 9, lines 12-14; page 9, line 29 to page 10, line 3; This allows the compound to be subjected to rapid “heat up” while at the same time not vaporizing the compound all at once. *Id.* at page 39, lines 22-25. See also, page 21, lines 13-17 (“[By] heating the substrate such that the compound is vaporized sequentially over no more than about a one second period of time . . . each segment of the compound has a heat-up time that is much less than one second.”)

In addition, according to the method of the present invention, aerosol with particles of a desired size range and stability can be formed by controlling the rate of vaporization, the rate of introduction of a carrier gas, and the mixing of the vapors and the carrier gas, thereby manipulating parameters that govern the physical processes of the formation of an aerosol from a vapor. In particular, the ratio of the vaporized compound to the volume of mixing air can be controlled by a number of methods, including regulating the vaporization rate of the compound. *Id.* at page 11, lines 7-18. In a preferred embodiment, this is accomplished by using moving

heating zone. The heating zone, which is smaller than the area on which the compound is deposited, is generated and moved with respect to the compound deposition area. *Id.* at page 39, line 25 to page 40, line 2. As the heating zone moves, exposed portions of the compound are progressively heated and compound molecules escape as vapors to mix with the carrier gas. *Id.* at page 9, lines 12-19. In this manner, the rate of vaporization can be controlled and, instead of vaporizing all of the compound at one time, the compound (in selected amounts) can be introduced into the gas stream over time. *Id.* at page 18, lines 24-27.

According to the MPEP § 2143, “to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations.” As Rabinowitz et al. does not teach or suggest generating a heating zone, all of the elements of amended Claim 1 are not taught or suggested by the reference. Accordingly, Claim 1 is not obvious over Rabinowitz et al. and Claims 4, 5, 16 and 18, which depend from Claim 1, are not obvious over the reference for at least the same reason.

Claims 7, 19-22, 29-33 and 43 stand rejected under 35 U.S.C. §103(a) over Rabinowitz et al. in view of U.S. Patent No. 4,947,874 to Brooks et al. (“Brooks et al.”).

Applicants respectfully disagree in view of the amended claims. As noted above, amended Claim 1 requires a “moving heating zone” which is not disclosed or suggested in Rabinowitz et al. or Brooks et al. As Claim 7 contains all of the limitations of Claim 1, Claim 7 is not obvious for the same reasons as Claim 1.

Similarly, Claim 19 is amended to recite a method for delivering a physiologically active compound to a patient comprising “depositing a physiologically active compound onto a substrate defining a compound deposition area; moving a heating zone with respect to the compound deposition area to progressively vaporize compound exposed to the heating zone; allowing the vapor to condense to form an aerosol; and administering the resulting aerosol to a patient” (emphasis added). Applicants submit that neither Rabinowitz et al. nor Brooks et al. discloses or suggests generating a moving heating zone and thus these references do not teach or suggest all of the elements of Claim 19. Accordingly, Claim 19 is not obvious over Rabinowitz

et al. in view of Brooks et al. and Claims 29-34, 43 and 45, which depend from Claim 19, are not obvious over the references for at least the same reason.

Finally, Claims 81 and 82 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rabinowitz et al. in view of U.S. Patent No. 3,949,743 to Shanbroom ("Shanbroom"). As stated above, claims 81-82 have been cancelled.

New Claim 84 also requires the use of a moving heating zone to progressively vaporize a physiologically active compound. This claim is patentable for the same reasons as Claims 1 and 19.

Accordingly, and in light of the foregoing arguments, Applicants respectfully submit that these amendments put the case in condition for allowance and request that the Examiner reconsider and withdraw all rejections based on 35 U.S.C §103.


Conclusion

Applicants appreciate the Examiner's careful and thorough review of the application and submit that the Examiner's concerns have been addressed by the amendments and remarks above. Applicants accordingly request the Examiner to withdraw all rejections and allow the application. In the event the Examiner believes a telephonic discussion would expedite allowance or help to resolve outstanding issues, prosecution of the application, then the Examiner is invited to call the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

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